UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **February 27, 2020**

RIGEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

0-29889	**94-3248524**
(Commission File No.)	(IRS Employer Identification No.)
1180 Veterans Boulevard **South San Francisco, CA** (Address of principal executive offices)	**94080** (Zip Code)

Registrant's telephone number, including area code: **(650) 624-1100**

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	**RIGL**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On February 27, 2020, Rigel Pharmaceuticals, Inc. ("Rigel") announced certain financial results for its fourth quarter and year ended December 31, 2019. A copy of Rigel's press release, titled "Rigel Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update," is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

The information in this report, including the exhibit hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Rigel, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release, dated February 27, 2020, titled "Rigel Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update."

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 27, 2020

RIGEL PHARMACEUTICALS, INC.

By: /s/ Dolly A. Vance
Dolly A. Vance

Executive Vice President, General Counsel and Corporate Secretary

Exhibit 99.1

Rigel Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update

Fourth quarter total revenues of $15.4 million; full year total revenues of $59.3 million

Fourth quarter net product sales of $13.8 million; full year net product sales of $43.8 million

Received $20.0 million payment from Grifols in first quarter 2020 for European approval of fostamatinib in adult patients with chronic ITP

Conference call and webcast today at 4:30PM Eastern Time

SOUTH SAN FRANCISCO, Calif., February 27, 2020 /PRNewswire/ -- Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) today reported financial results for the fourth quarter and full year ended December 31, 2019, including sales of TAVALISSE® (fostamatinib disodium hexahydrate) tablets, for the treatment of adults with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

"We are entering 2020 with a clear plan to drive shareholder value for Rigel," said Raul Rodriguez, Rigel's president and CEO. "We see substantial opportunities for TAVALISSE to meet patient needs in the growing adult chronic ITP market, particularly as an early line therapy. Utilization in these less refractory patients continues to grow with the support of ongoing physician education and data generation. To expand the range of TAVALISSE indications, we are conducting a Phase 3 trial in warm AIHA and expect to complete patient enrollment midyear. In addition, we are extremely excited about the potential of our early stage candidates and are currently exploring partnership opportunities that would enable Rigel to realize near-term value while also participating meaningfully in the upside of these programs."

Business Update

At the 61st American Society of Hematology (ASH) Annual Meeting & Exposition in December 2019, the company presented post-hoc data analysis from its Phase 3 clinical program of TAVALISSE in adult patients with chronic ITP. In this analysis, 32 patients received fostamatinib as a second-line therapy, of which, 78% (25/32) achieved ≥1 platelet count of ≥50,000/μL (without rescue therapy). Adverse events were manageable and consistent with those previously reported with fostamatinib. These data highlight the potential benefit of using TAVALISSE in earlier lines of therapy.

In February 2020, Rigel received a $20.0 million payment from its collaborative partner Grifols, S.A. (Grifols). The payment is comprised of $17.5 million for the European Commission's approval of the marketing authorization application for fostamatinib for the treatment of chronic immune thrombocytopenia in adult patients who are refractory to other treatments and a $2.5 million creditable advance royalty payment based on the terms of the collaboration agreement. Fostamatinib will be marketed in Europe under the brand name TAVLESSE™ (fostamatinib). Grifols is planning to launch the product in the second quarter of 2020.

Enrollment is ongoing in Rigel's Phase 3 pivotal trial in warm AIHA, FORWARD (Fostamatinib Research in Warm Antibody AIHA Disease). A total of 34 patients have been randomized to date. The trial remains on track to complete enrollment in mid-2020.

In February 2020, Rigel's partner Kissei Pharmaceuticals Co., Ltd. (Kissei) was granted orphan drug designation from the Japanese Ministry of Health, Labour and Welfare for R788 (fostamatinib) in chronic idiopathic thrombocytopenic purpura.

Financial Update

For the fourth quarter of 2019, Rigel reported a net loss of $17.2 million, or $0.10 per share, compared to net income of $3.2 million, or $0.02 per share, in the same period of 2018.

In the fourth quarter of 2019, total revenues were $15.4 million, consisting of $13.8 million in net product sales and $1.6 million in contract revenues from collaborations. Net product sales of $13.8 million increased by 90% compared to $7.3 million in the fourth quarter of 2018. This increase reflects the expanding patient and prescriber base for TAVALISSE and the growing persistency rate for refills at month 4, which is approximately 54%.

Contract revenues from collaborations of $1.6 million for the fourth quarter ended December 31, 2019 consists of a $1.5 million fee earned pursuant to an amendment of the license and collaboration agreement with Aclaris Therapeutics, Inc. (Aclaris) in October 2019, as well as deferred revenue from Rigel's collaboration with Grifols related to the performance of certain research and development services.

Rigel reported total costs and expenses of $32.7 million in the fourth quarter of 2019, compared to $35.3 million for the same period in 2018. The decrease in costs and expenses was primarily due to decreases in personnel-related expenses and various third-party costs.

For the full year ended December 31, 2019, Rigel reported a net loss of $66.9 million, or $0.40 per share, compared to a net loss of $70.5 million, or $0.44 per share, for the same period of 2018.

Rigel reported total revenues of $59.3 million for the year ended December 31, 2019, consisting of $43.8 million in net product sales and $15.5 million in revenues related to Rigel's collaboration agreements with Grifols, Kissei, Aclaris, and Impact Biomedicines, Inc.

Total costs and expenses for the year ended December 31, 2019, were $128.4 million, compared to $117.2 million, for the same period of 2018. The increase in total costs and expenses was primarily due to the increases in third party costs related to Rigel's ongoing pivotal Phase 3 study in warm AIHA, personnel-related costs, on-going commercialization of TAVALISSE in adult chronic ITP, and research and development costs related to its Phase 1 study in RIP.

As of December 31, 2019, Rigel had cash, cash equivalents and short-term investments of $98.1 million, compared to $128.5 million as of December 31, 2018. Rigel previously announced that in September 2019, we entered into a $60.0 million term loan credit facility with MidCap Financial. At closing,
$10.0 million was funded to Rigel in an initial tranche. The facility also gives Rigel the ability to access an additional $50.0 million, of which $40.0 million is subject to the achievement of certain customary conditions.

Conference Call and Webcast with Slides Today at 4:30pm Eastern Time

Rigel will hold a live conference call and webcast today at 4:30pm Eastern Time (1:30pm Pacific Time).

Participants can access the live conference call by dialing (877) 407-3088 (domestic) or (201) 389-0927 (international). The conference call and accompanying slides will also be webcast live and can be accessed from the Investor Relations section of the company's website at www.rigel.com. The webcast will be archived and available for replay after the call via the Rigel website.

About ITP

In patients with ITP (immune thrombocytopenia), the immune system attacks and destroys the body's own blood platelets, which play an active role in blood clotting and healing. Common symptoms of ITP are excessive bruising and bleeding. People suffering with chronic ITP may live with an increased risk of severe bleeding events that can result in serious medical complications or even death. Current therapies for ITP include steroids, blood platelet production boosters (TPO-RAs) and splenectomy. However, not all patients respond to existing therapies. As a result, there remains a significant medical need for additional treatment options for patients with ITP.

About AIHA

Autoimmune hemolytic anemia (AIHA) is a rare, serious blood disorder in which the immune system produces antibodies that result in the destruction of the body's own red blood cells. AIHA affects approximately 45,000 adult patients in the U.S. and can be a severe, debilitating disease. To date, there are no disease-targeted therapies approved for AIHA, despite the unmet medical need that exists for these patients. Warm antibody AIHA (wAIHA), the most common form of AIHA, is characterized by the presence of antibodies that react with the red blood cell surface at body temperature.

About R835[1]

The investigational candidate, R835, is an orally available, potent and selective inhibitor of IRAK1 and IRAK4 that has been shown preclinically to block inflammatory cytokine production in response to toll-like receptor (TLR) and the interleukin-1 receptor (IL-1R) family signaling. TLRs and IL-1Rs play a critical role in the innate immune response, and dysregulation of these pathways can lead to a variety of inflammatory pathological conditions. R835 treatment demonstrates amelioration of clinical symptoms in multiple rodent models of inflammatory disease including psoriasis, arthritis, lupus, multiple sclerosis and gout. The safety and efficacy of R835 has not been established by the FDA or any healthcare authority.

About R552[1]

The investigational candidate, R552, is an orally available, potent and selective inhibitor of receptor-interacting protein kinase (RIP1). RIP1 is believed to play a critical role in necroptosis. Necroptosis is a form of regulated cell death where the rupturing of cells leads to the dispersion of their inner contents, which induces immune responses and enhances inflammation. In preclinical studies, R552 prevented joint and skin inflammation in a RIP1-mediated murine model of inflammation and tissue damage. The safety and efficacy of R552 has not been established by the FDA or any healthcare authority.

About TAVALISSE

Indication

TAVALISSE® (fostamatinib disodium hexahydrate) tablets is indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

Important Safety Information

Warnings and Precautions

- Hypertension can occur with TAVALISSE treatment. Patients with pre-existing hypertension may be more susceptible to the hypertensive effects. Monitor blood pressure every 2 weeks until stable, then monthly, and adjust or initiate antihypertensive therapy for blood pressure control maintenance during therapy. If increased blood pressure persists, TAVALISSE interruption, reduction, or discontinuation may be required.
- Elevated liver function tests (LFTs), mainly ALT and AST, can occur with TAVALISSE. Monitor LFTs monthly during treatment. If ALT or AST increase to >3 x upper limit of normal, manage hepatotoxicity using TAVALISSE interruption, reduction, or discontinuation.
- Diarrhea occurred in 31% of patients and severe diarrhea occurred in 1% of patients treated with TAVALISSE. Monitor patients for the development of diarrhea and manage using supportive care measures early after the onset of symptoms. If diarrhea becomes severe (≥Grade 3), interrupt, reduce dose or discontinue TAVALISSE.
- Neutropenia occurred in 6% of patients treated with TAVALISSE; febrile neutropenia occurred in 1% of patients. Monitor the ANC monthly and for infection during treatment. Manage toxicity with TAVALISSE interruption, reduction, or discontinuation.
- TAVALISSE can cause fetal harm when administered to pregnant women. Advise pregnant women the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 1 month after the last dose. Verify pregnancy status prior to initiating TAVALISSE. It is unknown if TAVALISSE or its metabolite is present in human milk. Because of the potential for serious adverse reactions in a breastfed child, advise a lactating woman not to breastfeed during TAVALISSE treatment and for at least 1 month after the last dose.

Drug Interactions

- Concomitant use of TAVALISSE with strong CYP3A4 inhibitors increases exposure to the major active metabolite of TAVALISSE (R406), which may increase the risk of adverse reactions. Monitor for toxicities that may require a reduction in TAVALISSE dose.
- It is not recommended to use TAVALISSE with strong CYP3A4 inducers, as concomitant use reduces exposure to R406.
- Concomitant use of TAVALISSE may increase concentrations of some CYP3A4 substrate drugs and may require a dose reduction of the CYP3A4 substrate drug.
- Concomitant use of TAVALISSE may increase concentrations of BCRP substrate drugs (eg, rosuvastatin) and P-Glycoprotein (P-gp) substrate drugs (eg, digoxin), which may require a dose reduction of the BCRP and P-gp substrate drug.

Adverse Reactions

- Serious adverse drug reactions in the ITP double-blind studies were febrile neutropenia, diarrhea, pneumonia, and hypertensive crisis, which occurred in 1% of TAVALISSE patients. In addition, severe adverse reactions occurred including dyspnea and hypertension (both 2%), neutropenia, arthralgia, chest pain, diarrhea, dizziness, nephrolithiasis, pain in extremity, toothache, syncope, and hypoxia (all 1%).
- Common adverse reactions (≥5% and more common than placebo) from FIT-1 and FIT-2 included: diarrhea, hypertension, nausea, dizziness, ALT and AST increased, respiratory infection, rash, abdominal pain, fatigue, chest pain, and neutropenia.

Please see www.TAVALISSE.com for full Prescribing Information.

To report side effects of prescription drugs to the FDA, visit www.fda.gov/medwatch or call 1-800-FDA-1088 (800-332-1088).

TAVALISSE is a trademark of Rigel Pharmaceuticals, Inc.

About Rigel (www.rigel.com)

Rigel Pharmaceuticals, Inc., is a biotechnology company dedicated to discovering, developing and providing novel small molecule drugs that significantly improve the lives of patients with immune and hematologic disorders, cancer and rare diseases. Rigel's pioneering research focuses on signaling pathways that are critical to disease mechanisms. The company's first FDA approved product is TAVALISSE® (fostamatinib disodium hexahydrate), the only oral spleen tyrosine kinase (SYK) inhibitor, for the treatment of adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment. The product has been approved by the European Commission for the treatment of chronic immune thrombocytopenia in adult patients who are refractory to other treatments, and will be marketed in Europe under the name TAVLESSE™ (fostamatinib).

Rigel's clinical programs include a Phase 3 study of fostamatinib in warm autoimmune hemolytic anemia (AIHA); a recently completed Phase 1 study of R835[1], a proprietary molecule from its interleukin receptor associated kinase (IRAK) inhibitor program; and an ongoing Phase 1 study of R552[1], a proprietary molecule from its receptor-interacting protein kinase (RIP) inhibitor program. In addition, Rigel has product candidates in clinical development with partners Aclaris Therapeutics, AstraZeneca, BerGenBio ASA, and Daiichi Sankyo.

[1]The product for this use or indication is investigational and has not been proven safe or effective by any regulatory authority.

Forward Looking Statements

This release contains forward-looking statements relating to, among other things, the commercial success of TAVALISSE in the U.S.; the commercialization of TAVLESSE in Europe and the timing thereof; Rigel's ability to grow utilization of TAVALISSE in early line therapy; the utility of fostamatinib in warm autoimmune hemolytic anemia (AIHA); Rigel's ability to complete enrollment in its phase 3 clinical trial for AIHA and the timing thereof; Rigel's ability to further develop its clinical stage product candidates; and Rigel's partnering efforts. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "potential", "may", "expects", and similar expressions are intended to identify these forward-looking statements. These forward-looking statements are based on Rigel's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with the commercialization and marketing of TAVALISSE; risks that the FDA, EMA or other regulatory authorities may make adverse decisions regarding fostamatinib; risks that TAVALISSE clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; risks that TAVALISSE may have unintended side effects, adverse reactions or incidents of misuses; the availability of resources to develop Rigel's product candidates; market competition; as well as other risks detailed from time to time in Rigel's reports filed with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the period ended September 30, 2019. Rigel does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein.

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RIGEL PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
	(unaudited)			
Revenues:				
Product sales, net	$ 13,829	$ 7,295	$ 43,772	$ 13,947
Contract revenues from collaborations	1,571	30,562	15,516	30,562
Total revenues	15,400	37,857	59,288	44,509
Costs and expenses:				
Cost of product sales	178	188	906	287
Research and development (see Note A)	14,247	13,767	52,885	46,903
Selling, general and administrative (see Note A)	18,312	21,370	74,588	70,002
Total costs and expenses	32,737	35,325	128,379	117,192
Income (loss) from operations	(17,337)	2,532	(69,091)	(72,683)
Interest income	464	696	2,532	2,203
Interest expense	(327)	-	(335)	-
Net income (loss)	$ (17,200)	$ 3,228	$ (66,894)	$ (70,480)
Net income (loss) per share, basic and diluted	$ (0.10)	$ 0.02	$ (0.40)	$ (0.44)
Weighted-average shares used in computing net income (loss) per share				
Basic	167,619	166,680	167,400	160,529
Diluted	167,619	167,617	167,400	160,529
Note A				
Stock-based compensation expense included in:				
Selling, general and administrative	$ 934	$ 1,470	$ 6,453	$ 5,383
Research and development	477	587	2,662	2,321
	$ 1,411	$ 2,057	$ 9,115	$ 7,704

SUMMARY BALANCE SHEET DATA
(in thousands)

	December 31,	
	2019	2018
Cash, cash equivalents and short-term investments	$ 98,078	$ 128,537
Total assets	147,569	139,109
Stockholders' equity	53,815	109,877